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November 30, 2011

Dr. Ruth Lunn, Director
Office of the Report on Carcinogens
DNTP NIEHS
P.O. Box 12233, MD K2-14
Research Triangle Park, NC 27709
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Re: Proposed National Toxicology Program (NTP) Review Process for the Report on Carcinogens

Dear Dr. Lunn:

Materion Brush Inc., formerly known as Brush Wellman Inc., submits these comments on the proposed Report on Carcinogens (RoC) review process announced at 76 *Federal Register* 67200 (October 31, 2011) and which was the subject of a public listening session on November 29, 2011. 76 *Federal Register* 71037 (November 16, 2011). In the October 31 *Federal Register* notice, the National Toxicology Program ("NTP") states that:

The NTP plans to post the finalized RoC review process on the RoC Web site (<http://ntp.niehs.nih.gov/go/rocprocess>) and present it at the next NTP Board of Scientific Counselors meeting on December 15, 2011.

The proposed process, as described summarily by the Proposed Report on Carcinogens Review Process ("Proposed Report") has four parts: (1) nomination and selection of candidate substances; (2) scientific evaluation of candidate substances, (3) public release of the draft RoC monograph and peer review, and (4) HHS approval and release of the latest edition of RoC. This proposed process is similar in many respects to the process that NTP has been using in preparing the biennial Report on Carcinogens. See NTP, *Tenth Report on Carcinogens* pp. I-1 to I-3. Materion Brush has first-hand familiarity with that process by virtue of commenting on the decision of the NTP to list beryllium and compounds in the Tenth Report as a class of substances "known to be human carcinogens." This Report changed the classification of beryllium and compounds from "reasonably anticipated to be human carcinogens" in the Second Report on Carcinogens in 1981.

NTP in the Tenth Report classified beryllium and compounds as substances known to be human carcinogens, incorrectly in Materion Brush's opinion and by the narrowest of margins in any event. The NTP Executive Committee Interagency Working (RG2), a governmental interagency group that assessed whether the information available for the nomination warranted this listing, voted by a close 6 to 5 majority to support the nomination. As noted in the Tenth Report, the decision to classify beryllium and compounds as a human carcinogen was based on two companion studies. As noted in public comments submitted in writing and at the NTP

Board of Scientific Counselors meeting, these two studies contained several flaws, which were also identified in the peer-reviewed literature. Further, it was noted that even if these flaws were ignored, classifying beryllium and compounds as a known human carcinogen based on these two studies would be a classification based on the lowest Standard Mortality Ratio calculated for any substance thus classified by the NTP.

Interestingly, the profile for beryllium and compounds in the Tenth Report devotes but a single paragraph to the subject of cancer studies in humans and contains no mention of the weaknesses of the studies, the strong debate in the literature and the flaws discussed during the RoC process. In contrast, multiple paragraphs, comprising three-fourths of the text of the entire profile, are devoted to each of the sections related to the properties, use, production, and exposure to beryllium and beryllium compounds.

In light of its experience with the RoC process, Materion Brush encourages the NTP to revise its process to avoid skewed, incomplete and uncritical analyses of the studies upon which a classification is based, to be better capable of considering the scientific merit of opposing points of view and to be more transparent and open throughout the RoC process.

For the purpose of supporting these overall objectives, Materion Brush requests that the proposed review process be changed in the following ways.

1. Clarification and Strengthening of the Role of Public Comment

The purposed process provides three opportunities for public comment:

- On the "draft concept paper" that is prepared for a substance proposed for evaluation after a nomination has been accepted;
- On the revised draft RoC Monograph that is prepared after interagency review of the initial draft RoC Monograph; and
- Orally at an external advisory group meeting to consider the revised draft RoC Monograph.

The proposed process does not require the NTP to ever acknowledge and respond to public comments. Such a requirement is necessary to assure the public that their comments are heard and understood and to be advised as to whether and why the NTP has or has not incorporated those comments into its action. This summary and response to public comments is needed at every level. The NTP staff, the NTP Board of Scientific Counselors and the NTP Director should be aware of the substance of public comments on a draft document before recommending and/or making the final determination whether to add a substance to the list of candidate substances for RoC evaluation.

The Office of the Report on Carcinogens should be aware of prior public comments on the draft concept paper before preparing a draft RoC Monograph for the candidate substance. When the draft RoC Monograph is circulated for interagency review, NTP should concurrently circulate its summary and response to prior public comments on the draft concept paper and make those comments available to each of the interagency reviewers. Likewise, when the revised draft RoC Monograph is submitted to the external advisory group, the external advisors should concurrently receive the summary and response to prior public comments on the draft RoC Monograph and have available to them the text of those comments for their review at their

discretion. In addition, before the NTP considers the peer review report, it should also prepare a summary of additional public comments presented at the external advisory group meeting. Finally, when the NTP prepares a response to the peer review report, it should concurrently prepare a response to public comments.

In sum, if the NTP solicits public comment on a RoC work product, it should forward a summary and response to those comments to any intra- or inter-agency reviewer or peer-reviewer of that work product or any document derived therefrom. Those reviewers should also be able to access the text of the public comments. In addition, the summary and response to prior public comments should be made publicly available whenever NTP issues a draft document for public comment. Such a protocol allows the commenter to determine whether its comments have been understood and fairly responded to rather than being misunderstood or otherwise avoided. Having this summary and response publicly available will also allow other potential commenter's to know the issues that are involved in NTP's proposed action and to comment upon them as well. These changes in the RoC process are consistent with and necessary to implement President Obama's Executive Order 13563, which states that agencies "must allow for public participation and an open exchange of ideas." 76 *Federal Register* 3821 (January 18, 2011). Without a response to public comments, there can be no open exchange of ideas.

Transparency and Openness in the Solicitation and Selection of External Peer Reviewers

The proposed process provides for NTP to submit the revised draft RoC Monograph for a substance to "an external advisory group (e.g., BSC or expert panel)" and to commence a meeting of that group for the purpose of "peer review." This peer review process will be only as valuable as the peer reviewers actually selected. To ensure the selection of informed and unbiased peer reviewers with expertise in the critical and likely areas of the controversial monograph, NTP should employ a transparent and open process. To do this, NTP should (1) publicly announce the solicitation of nominations for an external advisory group; (2) make publicly available the names of the candidates for the group, whether nominated by the public or solicited by the NTP or its contractors; and (3) make publicly available the names and CVs of the persons selected to serve on the group. To assure balance, the NTP should screen out from service on the group, persons with a financial interest in the classification of the substance under consideration or those who have previously opined on the classification of the substance or the critical issues upon which classification will depend for the substance under consideration.

These changes are all consistent with and required by President Obama's March 9, 2009 Memorandum on Scientific Integrity on the Director of the Office of Science and Technology Policy's December 17, 2010 Memorandum which provides further guidance on this subject. The President's Memorandum directs:

To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking. The selection of scientists and technology professionals for positions in the executive branch should be based on their scientific and technological knowledge, credentials, experience, and integrity.

The Director's Memorandum states that recruitment of advisory groups tasked with giving scientific advice "should be as transparent as practicable" . . . with an invitation for the public to recommend individuals for consideration and self-nominations to be submitted." Furthermore,

this Memorandum directs that professional biographical information on candidates "should be made widely available to the public (e.g., via a website)." In addition, the Memorandum states that group membership "should be fairly balanced in terms of points of view represented" with members selected based on their "expertise, knowledge, and contribution to the relevant subject areas."

2. NTP Should Forward These and Other Comments to the NTP Board of Scientific Counselors

Because NTP intends to present its final RoC review process to the NTP Board of Scientific Counselors at its December 15, 2011 meeting the NTP, it is unclear to Materion Brush how NTP within 15 days will adequately consider these comments, make any changes to the draft report, issue the final report and transmit it to the Board of Scientific Counselors before its meeting. NTP should take additional time to prepare its final report. In any event, NTP should forward these and other comments to the Board along with the final report on the RoC process. NTP should also prepare, forward and post a summary and response to these public comments for the reasons stated above.

Please contact me at 216-383-6848 if you have any questions concerning these comments.

Sincerely,

[Redacted]

Marc E. Kolan
Vice President
Environmental Health and Safety

MEK/elm